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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,569	02/21/2002	Gholam-Reza Zadno-Azizi	38349-0102D	4156

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/081,569	ZADNO-AZIZI ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 20-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-27 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Ex Parte Quayle*

1. This application is in condition for allowance except for the following formal matters:  
see below.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

### *Response to Amendment*

2. The amendment filed January 17, 2006 has been entered. The changes to the claims have been approved. All pending claims 20-27 are being considered for further examination on the merits.
3. The Declaration under 37 CFR 1.132 filed January 17, 2006 is sufficient to overcome the rejection of claims 20 and 23 based upon lack of enablement under 112, first paragraph. Claims 20-25 do receive priority benefit of the parent applications and have an effective filing date of September 16, 1997. Accordingly, the rejection of claims 20-25 under 35 U.S.C. 103(a) is withdrawn because Alferness et al. (USPN 6,293,951) is not effective as prior art.

*Response to Arguments*

4. Applicant's arguments filed January 17, 2006 have been fully considered but they are not persuasive. With respect to claims 26 and 27 and Andersen et al., applicant argues that the sutures that secure the two folded wire rings of the stent together create holes and other imperfections that form leak paths for air to flow across and through the device even with the valve is closed. Thus, although the valve itself might be attached to the stent by gluing or welding, the device would still have suture holes at the attachment of the folded wire rings that form the stent. The examiner disagrees. From the arrangement of the wire rings shown in FIG. 1, it would appear that the sutures (not shown) would be tied around a portion of each ring such that the rings are secured together. The securing sutures would not create holes because the sutures are not going through any material in which to make holes. Therefore, there would be no "suture holes" at the attachment of the folded wire rings that would form leak paths for air to flow across and through the device.

5. The valve of Andersen et al. can be mounted on the stent by welding or gluing. See column 2, lines 35-37. As can be seen in FIG. 2, the points where the valve can be welded or glued to the stent are at the points of contact between the valve and stent. There exist areas between those points of contact that the valve is not attached to the stent any other structure. When the device is implanted in a bronchial passageway, air may flow across the device and through the bronchial passageway at these areas where the valve is not glued, welded or otherwise attached to the stent or any other structure. Therefore, Andersen et al. alone or combined with Moasser will not meet the limitations of claims 26 and 27 as amended.

***Specification***

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the valve being dimensioned for placement in a *bronchial passageway*; the valve allowing and restricting *air flow* therethrough when in an open and closed configuration, respectively; the device having a construction that completely blocks *air flow* through the *bronchial passageway* when the valve is in the closed configuration; the frame self-expanding within a *bronchial passageway* sufficiently to anchor the device within the *bronchial passageway*; no *air flow* occurring across the flow control device and through the *bronchial passageway* when the valve is in the closed configuration. These claimed limitations must be included in the specification.

***Allowable Subject Matter***

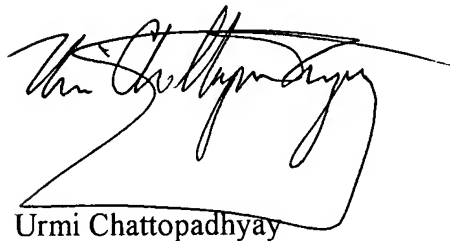
7. Claims 20-27 are allowed.

Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

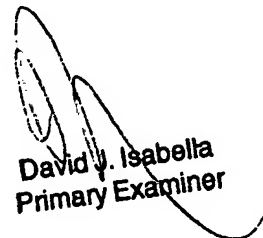
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella  
Primary Examiner